Remarks

Claims 1-3 and 11-26 are pending in this application. Claims 25 and 26 have been withdrawn by the Examiner as being drawn to a non-elected invention, subject to allowance of the product claims. Claims 4-10 have been cancelled according to a Preliminary Amendment filed on March 21, 2005. Claims 1, 20, 24 and 26 have been amended without prejudice as discussed below. Claim 13 was amended to correct a typographical error. No new matter has been added to the application by any of the amendments.

35 U.S.C. §112 rejections

At pages 3-10 of the Office Action, claims 1-3 and 11-24 have been rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for preventing an autoimmune disorder. While Applicants respectfully disagree with and traverse this rejection, claims 1, 20, 24 and 26 have been amended to delete "preventing in order to expedite the examination of this application, without prejudice to the filing of one or more continuation applications directed to the canceled subject matter. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

At page 10 of the Office Action, claim 3 has been rejected under 35 U.S.C. §112, second paragraph, alleging that the sterol absorption inhibitor of Formula (II) in claim 3 lacks antecedent basis from claim 1.

Applicants respectfully traverse this rejection and request that the rejection be reconsidered and withdrawn. The sterol absorption inhibitor of Formula (II) is a species of the genus of sterol absorption inhibitors described as Formula (I) in claim 1. More specifically, in claim 3 the Ar^2 group of Formula (I) is an R^4-substituted aryl, wherein R^4 is a halogen (fluorine). The Ar^3 group of Formula (I) is an R^5-substituted aryl where R^5 is $-OR^6$ and R^6 is hydrogen (i.e., OH). Ar^1 is an R^4-substituted aryl, wherein R^4 is a halogen (fluorine), m is 0, q is 1, R^1 is hydrogen, R is $-OR^6$ where R^6 is hydrogen, Y_n is CH_2 where n is 1, Z_p is CH_2 where p is 1, and r is 0. Therefore, since Formula (II) of claim 3 is a species of Formula (I) of claim 1, the rejection under 35 U.S.C. §112, second paragraph, should be withdrawn and claim 3 should be allowed.

35 U.S.C. §102(b) rejection

At page 11 of the Office Action, claims 1-3, 12-17, and 20-24 have been rejected under 35 U.S.C. §102(b) as anticipated by Liu et al. (U.S. Patent No. 6,569,879) (hereinafter "Liu"). For brevity, the reasons for rejection are not repeated herein but are set forth in the Office Action and are incorporated by reference herein.

Applicants respectfully traverse this rejection and request that the rejection be reconsidered and withdrawn. First, Applicants respectfully assert that a rejection under 35 U.S.C. §102(b) is improper. The present application was filed on November 4, 2003. The Liu patent granted on May 27, 2003, which is less than one year before the filing date of the present application. Further, the Liu patent application was published as US2002/0173663 on November 21, 2002, which is less than one year before the filing date of the present application. For these reasons, Applicants believe that a rejection under 35 U.S.C. §102(b) over Liu is improper and requests that the rejection be withdrawn.

Moreover, even if the Liu patent was a proper 102 reference for citation, it does not provide any teachings that would anticipate the pending claims. The Liu patent teaches aryloxyacetic acids and pharmaceutically acceptable salts and products thereof which are useful as PPAR agonists, particularly in the treatment of Type 2 diabetes mellitus.

The present invention claims a method of treating an autoimmune disorder in a subject, comprising the step of administering to a subject in need of such treatment an effective amount of at least one sterol absorption inhibitor of Formulae I and III-IX or a pharmaceutically acceptable salt or solvate thereof.

The Office Action asserts that the Liu patent teaches a method for treating inflammatory conditions, including rheumatoid arthritis and multiple sclerosis by administering a sterol inhibitor, ezetimibe. Applicants respectfully disagree. The Liu patent teaches a method of treating inflammatory conditions, including rheumatoid arthritis and multiple sclerosis by administering an effective amount of a PPAR agonist. The Liu patent does not teach the use of ezetimibe, a sterol inhibitor claimed by the present invention, for the treatment of rheumatoid arthritis and multiple sclerosis. The Liu patent discloses that the PPAR agonist may be used in

combination with lipid lowering drugs to treat hypercholesterolemia, atherosclerosis, hyperlipidemia, hypertriglyceridemia, dyslipidemia, high HDL and low HDL (see col. 11, lines 19-42).

Therefore, because the sterol inhibitor ezetimibe is not described either alone or in combination for the treatment of rheumatoid arthritis and multiple sclerosis in the Liu patent, the Liu patent does not anticipate the presently claimed invention.

Finally, the Office Action asserts that the Liu patent anticipates the present invention by teaching a HMG-CoA reductase inhibitor such as atorvastatin and simvastatin. The Liu patent discloses the combination of a PPAR agonist and a HMG-CoA reductase inhibitor to treat hypercholesterolemia, atherosclerosis, hyperlipidemia, hypertriglyceridemia, dyslipidemia, high LDL, and low LDL. The present invention does not claim combining a PPAR agonist and a HMG-CoA reductase inhibitor. The present invention does not claim treating hypercholesterolemia, atherosclerosis, hyperlipidemia, hypertriglyceridemia, dyslipidemia, high LDL, and low LDL. Rather, the present invention claims using a sterol absorption inhibitor or a pharmaceutically acceptable salt or solvate thereof to treat an individual with an autoimmune disorder. Because the present invention does not require using a PPAR agonist in combination with a HMG-CoA reductase inhibitor to treat an autoimmune disorder, the Liu patent does not anticipate the presently claimed invention.

For the aforementioned reasons, the rejection under 35 U.S.C. §102(b) should be withdrawn and claims 1-3, 12-17, and 20-24 should be allowed.

35 U.S.C. 103(a) rejection

At pages 12-13 of the Office Action, claims 11 and 18-19 are rejected as being obvious under 35 U.S.C. §103(a) over the Liu patent as applied to claims 1-3, 12-17, and 20-24 above, in view of Vaccaro et al. (U.S. Patent No. 5,656,624) (hereinafter "Vaccaro") and Somers (U.S. Patent No. 6,147,250) (hereinafter "Somers").

As discussed above, the Liu patent is not a valid reference under 35 U.S.C. §102(b) as applied above, therefore the §103(a) rejection based upon the above-recited 35 U.S.C. §102(b) rejection is improper and should be withdrawn.

Even if the Liu patent was a proper reference under 35 U.S.C. §102/103(a), as discussed above the Liu patent does not provide any teachings which would render the present invention obvious. As noted above, Liu does not suggest or disclose use of at least one sterol absorption inhibitor of Formulae I or III-IX or a pharmaceutically acceptable salt or solvate thereof for treating an autoimmune disorder. Neither Vaccaro nor Somers suggest or disclose use of at least one sterol absorption inhibitor of Formulae I or III-IX or a pharmaceutically acceptable salt or solvate thereof for treating an autoimmune disorder and therefore do not overcome the deficiencies of the Liu patent. Accordingly, the present claims are not obvious over Liu in view of Vaccaro and Somers and therefore the rejection under 35 U.S.C. §103(a) should be withdrawn and claims 11 and 18-19 should be allowed.

Double Patenting

At page 13-14 of the Office Action, claims 1-3, 11, 17-21, and 24 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 16, 27, and 29-32 of U.S. Patent No. 7,053,080 (hereinafter the "'080 patent"); and claims 1-3, 17, 19-20, 23-27, 29-30, and 32 of U.S. Patent No. 7,071,181 (hereinafter the "'181 patent").

Also, claims 1-3, 11, 17-21, and 24 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-3, 35-37, 44, and 47 of copending Application Kosoglou et al. (U.S. Patent Application No. 2002/0147184); claims 1-2, 34-38, 46, and 49 of copending Application Kosoglou et al. (U.S. Patent Application No. (2003/0069221); claims 19-20 of copending Application Fine et al. (U.S. Patent Application No. 2004/0092500); claims 1-3, 16, 27, and 29-32 of copending Davis et al. (U.S. Patent Application No. 2006/0009399); and claims 1-15 and 21-25 of copending Application Veltri (U.S. Patent Application No. 2006/0069080).

Further, claims 1-3, 11, 17-21, and 24 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28 and 33-35 of the '080 patent and claims 21-22, 28, 31, and 33-34 of the '181 patent in view of Liu et al., Vaccaro et al. and Somers as applied to claims 1-24 above and in further view of the '080 patent, the '181 patent, and Fine et al. (U.S. Patent Application No. 2004/0092500).

Finally, claims 1-3, 11, 17-21, and 24 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-2, 10, and 13-18 of copending Application Fine et al. (U.S. Patent No. 2004/0092500), claims 28 and 33-35 of copending Applications Davis et al. (U.S. Patent Application No. 2006/0009399), and claims 16-20 and 31-39 of copending Application Veltri (U.S. Patent Applications No. 2006/0069080) in view of Liu et al., Vaccaro et al., and Somers as applied to claims 1-24 above and in further view of the '080 patent, the '181 patent, and Fine et al. (U.S. Patent Application No. 2004/0092500).

Applicants respectfully disagree with and traverse these rejections. However, to advance prosecution, a terminal disclaimer is submitted with this response to terminally disclaim the terminal part of the statutory term of any patent granted on the present application that would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. § 154 to 156 and 173 of Fine et al. (U.S. Patent Application No. 2004/0092500) (Serial No. 10/701,244) subject to the conditions noted in the terminal disclaimer.

With respect to the other references cited in the obviousness-type double patenting rejections, Applicants respectfully disagree with the rejections and request that the rejections be reconsidered and withdrawn.

According to M.P.E.P. § 804(II)(B)(1), the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. §103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

(A) Determine the scope and content of a patent claim relative to a claim in the application at issue;

(B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;

(C) Determine the level of ordinary skill in the pertinent art; and

(D) Evaluate any objective indicia of nonobviousness.

The conclusion of obviousness-type double patenting is made in light of these factual determinations. Any obviousness-type double patenting rejection should make clear: (A) The differences between the inventions defined by the conflicting claims - a claim in the patent compared to a claim in the application; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the patent. When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle GmbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992).

Claims 1-3, 11, 17-21, and 24 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 16, 27, and 29-32 of the '080 patent. Claim 1 of the '080 patent recites a composition comprising at least one obesity control medication and at least one sterol absorption inhibitor or at least one 5α-stanol absorption inhibitor, or pharmaceutically acceptable salts or solvates thereof. Claim 3 depends from claim 1 and further recites a compound of formula II. Claim 16 depends from claim 1 and further recites amounts of sterol absorption inhibitor. Claim 27 depends from claim 1 and further recites a pharmaceutical composition for treating obesity or lowering the concentration of a sterol or 5α-stanol in a mammal. Claim 29 recites a therapeutic combination comprising at least one obesity control medication and at least one sterol absorption inhibitor or at least one 5α-stanol absorption inhibitor for treating obesity or lowering the concentration of a sterol or 5α-stanol in a mammal. Claim 30 depends from claim 29 and further recites that the sterol absorption inhibitor is represented by Formula I. Claim 31 depends from claim 29 and further recites that the obesity control medication is administered concomitantly with the sterol

absorption inhibitor. Claim 32 depends from claim 29 and further recites that the obesity control medication and the sterol absorption inhibitor are present in separate treatment compositions.

In contrast, claim 1 of the present application recites a method for treating an autoimmune disorder in a subject comprising administering sterol absorption inhibitor(s) of Formulae I or III-IX to treat the autoimmune disorder. Clearly, the cited claims of the '080 patent do not suggest or disclose treatment of autoimmune disorders. One of ordinary skill in the art would not be motivated by a disclosure of a composition comprising obesity control medication and at least one sterol absorption inhibitor in the '080 patent to treat autoimmune disorders as claimed in the present application. Therefore, claim 1 of the present application is not obvious over claims 1-3, 16, 27, and 29-32 of the '080 patent. Claims 2-3, 11, and 17-19 of the present application depend from claim 1 and are not obvious over the cited claims of the '080 patent for the same reasons as those set forth above with respect to claim 1. Similarly, claims 20 and 24 of the present application recite methods for treating an autoimmune disorder using a compound of Formula II or treating rheumatoid arthritis comprising administering sterol absorption inhibitor(s) of Formulae I or III-IX. Claim 21 of the present application depends from claim 20 and includes all of the limitations of claim 20. As discussed above, one of ordinary skill in the art would not be motivated by a disclosure of a composition comprising obesity control medication and at least one sterol absorption inhibitor in the '080 patent to treat autoimmune disorders or rheumatoid arthritis as claimed in the present application. Therefore, claims 20, 21 and 24 of the present application are not obvious over claims 1-3, 16, 27, and 29-32 of the '080 patent.

Claims 1-3, 11, 17-21, and 24 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 17, 19-20, 23-27, 29-30, and 32 of the '181 patent. Claim 1 of the '181 patent recites a composition comprising at least one antidiabetic medication and at least one sterol absorption inhibitor or at least one 5α-stanol absorption inhibitor, or pharmaceutically acceptable salts or solvates thereof. Claim 2 depends from claim 1 and further recites that the sterol absorption inhibitor or 5α-stanol absorption inhibitor is represented by Formula I. Claim 3 depends from claim 1 and further recites a

compound of Formula II. Claim 17 depends from claim 1 and further recites amounts of sterol absorption inhibitor. Claim 19 depends from claim 1 and further recites a pharmaceutical composition for treating diabetes or lowering the concentration of a sterol or 5α-stanol in a mammal. Claim 20 depends from claim 19 and further recites a pharmaceutical composition for treating Type I or Type 2 diabetes or lowering the concentration of a sterol or 5α-stanol in a mammal. Claim 23 recites a therapeutic combination comprising at least one selected antidiabetic medication and at least one sterol absorption inhibitor or at least one 5α-stanol absorption inhibitor for treating diabetes or lowering the concentration of a sterol or 5α-stanol in a mammal. Claim 24 depends from claim 23 and further recites that the sterol absorption inhibitor is represented by Formula I. Claim 25 depends from claim 23 and further recites that the sterol absorption inhibitor is represented by Formula II. Claim 26 depends from claim 23 and further recites that the antidiabetic medication is administered concomitantly with the sterol absorption inhibitor. Claim 27 depends from claim 23 and further recites that the antidiabetic medication and the sterol absorption inhibitor are present in separate treatment compositions. Claim 29 recites a composition comprising at least one antidiabetic medication and at least one substituted azetidinone, salt or solvate. Claim 30 depends from claim 29 and recites a pharmaceutical composition for treating diabetes or lowering the concentration of a sterol or 5α-stanol in a subject. Claim 32 recites a therapeutic combination comprising at least one selected antidiabetic medication and at least one substituted azetidinone, salt or solvate for treating diabetes or lowering the concentration of a sterol or 5α-stanol in a subject.

In contrast, claim 1 of the present application recites a method for treating an autoimmune disorder in a subject comprising administering sterol absorption inhibitor(s) of Formulae I or III-IX to treat the autoimmune disorder. Clearly, the cited claims of the '181 patent do not suggest or disclose treatment of autoimmune disorders. One of ordinary skill in the art would not be motivated by a disclosure of a composition comprising antidiabetic medication and at least one sterol absorption inhibitor in the '181 patent to treat autoimmune disorders as claimed in the present application. Therefore, claim 1 of the present application is not obvious over claims 1-3, 17, 19-20, 23-27, 29-30, and 32 of the '181 patent.

Claims 2-3, 11, and 17-19 of the present application depend from claim 1 and are not obvious over the cited claims of the '181 patent for the same reasons as those set forth above with respect to claim 1. Similarly, claims 20 and 24 of the present application recite methods for treating an autoimmune disorder using a compound of Formula II or treating rheumatoid arthritis comprising administering sterol absorption inhibitor(s) of Formulae I or III-IX. Claim 21 of the present application depends from claim 20 and includes all of the limitations of claim 20. As discussed above, one of ordinary skill in the art would not be motivated by a disclosure of a composition comprising antidiabetic medication and at least one sterol absorption inhibitor in the '181 patent to treat autoimmune disorders or rheumatoid arthritis as claimed in the present application. Therefore, claims 20, 21 and 24 of the present application are not obvious over claims 1-3, 17, 19-20, 23-27, 29-30, and 32 of the '181 patent.

As discussed above, claims 1-3, 11, 17-21, and 24 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-3, 35-37, 44, and 47 of copending Application Kosoglou et al. (U.S. Patent Application No. 2002/0147184); claims 1-2, 34-38, 46, and 49 of copending Application Kosoglou et al. (U.S. Patent Application No. (2003/0069221); claims 1-3, 16, 27, and 29-32 of copending Davis et al. (U.S. Patent Application No. 2006/0009399); and claims 1-15 and 21-25 of copending Application Veltri (U.S. Patent Application No. 2006/0069080).

Claims 1-3, 35-37, 44, and 47 of copending Application Kosoglou et al. (U.S. Patent Application No. 2002/0147184) relate to compositions comprising at least one blood modifier for vascular conditions and at least one sterol absorption inhibitor. Similarly, claims 1-2, 34-38, 46, and 49 of copending Application Kosoglou et al. (U.S. Patent Application No. (2003/0069221) relate to compositions comprising at least one cardiovascular agent and at least one sterol absorption inhibitor. Copending Davis et al. (U.S. Patent Application No. 2006/0009399) is a division of the '080 patent and has claims similar to that patent discussed in detail above. Claims 1-15 and 21-25 of copending Application Veltri (U.S. Patent Application No. 2006/0069080) relate to compositions comprising at least one selective CB_1 antagonist and at least one cholesterol lowering compound.

In contrast, claim 1 of the present application recites a method for treating an autoimmune disorder in a subject comprising administering sterol absorption inhibitor(s) of Formulae I or III-IX to treat the autoimmune disorder. Clearly, the cited claims of the above Kosoglou et al., Davis et al. and Veltri references do not suggest or disclose treatment of autoimmune disorders. One of ordinary skill in the art would not be motivated by a disclosure of compositions comprising blood modifiers, cardiovascular agents, or CB_1 antagonists and at least one sterol absorption inhibitor to treat autoimmune disorders as claimed in the present application. Therefore, claim 1 of the present application is not obvious over the cited claims of the Kosoglou et al., Davis et al. and Veltri references. Claims 2-3, 11, and 17-19 of the present application depend from claim 1 and are not obvious for the same reasons as those set forth above with respect to claim 1. Similarly, claims 20 and 24 of the present application recite methods for treating an autoimmune disorder using a compound of Formula II or treating rheumatoid arthritis comprising administering sterol absorption inhibitor(s) of Formulae I or III-IX. Claim 21 of the present application depends from claim 20. Therefore, claims 20, 21 and 24 of the present application are not obvious over the cited claims of the Kosoglou et al., Davis et al. and Veltri references.

As discussed above, claims 1-3, 11, 17-21, and 24 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28 and 33-35 of the '080 patent and claims 21-22, 28, 31, and 33-34 of the '181 patent in view of Liu et al., Vaccaro et al. and Somers as applied to claims 1-24 above and in further view of the '080 patent, the '181 patent, and Fine et al. (U.S. Patent Application No. 2004/0092500). As noted above, the Liu patent is not a valid reference under 35 U.S.C. §102(b) as applied above, therefore the nonstatutory obviousness-type double patenting based upon the above-recited 35 U.S.C. §102(b) rejection is improper and should be withdrawn. Even if the Liu patent was a proper reference under 35 U.S.C. §102, as discussed above the Liu patent does not provide any teachings which would render the present invention obvious. As noted above, Liu does not suggest or disclose use of at least one sterol absorption inhibitor of Formulae I or III-IX or a pharmaceutically acceptable salt or solvate thereof for treating an autoimmune disorder. Neither Vaccaro nor Somers

suggests or discloses use of at least one sterol absorption inhibitor of Formulae I or III-IX or a pharmaceutically acceptable salt or solvate thereof for treating an autoimmune disorder and therefore do not overcome the deficiencies of the Liu patent. The cited claims of the '080 patent and the '181 patent do not suggest or disclose use of at least one sterol absorption inhibitor of Formulae I or III-IX or a pharmaceutically acceptable salt or solvate thereof for treating an autoimmune disorder and therefore do not overcome the deficiencies of the Liu patent. A terminal disclaimer has been filed with respect to the Fine et al. reference, which renders any nonstatutory obviousness-type double patenting rejection based upon this reference as moot.

As noted above, claims 1-3, 11, 17-21, and 24 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-2, 10, and 13-18 of copending Application Fine et al. (U.S. Patent No. 2004/0092500), claims 28 and 33-35 of copending Application Davis et al. (U.S. Patent Application No. 2006/0009399), and claims 16-20 and 31-39 of copending Application Veltri (U.S. Patent Applications No. 2006/0069080) in view of Liu et al., Vaccaro et al, and Somers as applied to claims 1-24 above and in further view of the '080 patent, the '181 patent, and Fine et al. (U.S. Patent Application No. 2004/0092500).

A terminal disclaimer has been filed with respect to the Fine et al. reference, which renders any nonstatutory obviousness-type double patenting rejection based upon this reference as moot. As discussed above, Davis et al. and Veltri do not suggest or disclose treatment of autoimmune disorders. One of ordinary skill in the art would not be motivated by a disclosure of compositions comprising obesity control medications or CB_1 antagonists and at least one sterol absorption inhibitor to treat autoimmune disorders as claimed in the present application. As noted above, the Liu patent is not a valid reference under 35 U.S.C. §102(b) as applied above, therefore the nonstatutory obviousness-type double patenting based upon the above-recited 35 U.S.C. §102(b) rejection is improper and should be withdrawn. Neither Vaccaro nor Somers suggests or discloses use of at least one sterol absorption inhibitor of Formulae I or III-IX or a pharmaceutically acceptable salt or solvate thereof for treating an autoimmune disorder. The cited

claims of the '080 patent and the '181 patent do not suggest or disclose use of at least one sterol absorption inhibitor of Formulae I or III-IX or a pharmaceutically acceptable salt or solvate thereof for treating an autoimmune disorder and therefore do not overcome the deficiencies of the cited reference claims.

None of the cited references claims methods for treating autoimmune diseases, as is presently claimed. Accordingly, Applicants respectfully request that the Terminal Disclaimer be entered of record and the rejections of claims 1-3, 11, 17-21, and 24 under the judicially created doctrine of obviousness-type double patenting be reconsidered and withdrawn.

CONCLUSION

For all of the foregoing reasons, Applicants submit that pending claims 1-3 and 11-26 comply with the requirements of 35 U.S.C. §112, are patentable over the cited references and in condition for allowance. Accordingly, reconsideration of the rejections and allowance of pending claims 1-3 and 11-26 are respectfully requested.

Should the Examiner have any questions regarding any of the foregoing or wish to discuss this application in further detail to advance prosecution, the Examiner is invited to contact Applicants' undersigned representative at the telephone number provided below.

Respectfully submitted,

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Date: June 8, 2007

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